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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,595	09/19/2003	Timothy A.M. Chuter	BSI-597US	3652
60117	7590	12/27/2007		
RATNER PRESTIA P.O. BOX 980 VALLEY FORGE, PA 19482			EXAMINER STROUD, JONATHAN R	
			ART UNIT	PAPER NUMBER
			3774	
			MAIL DATE	DELIVERY MODE
			12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,595

Applicant(s)

CHUTER, TIMOTHY A.M.

Examiner

Jonathan R. Stroud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) ~~1-25~~ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 1930 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/09/2004, 05/03/2004, 04/06/2004.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-15 in the reply filed on July 7, 2006 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities: on line 11 of page 22 of the specification, applicant makes reference to figure 350 in Fig. 13. "Fig. 13" is believed to be in error for -- Fig. 14 --, which contains the relevant figures and is listed at the beginning of the paragraph "With reference to FIGS. 14-22".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

4. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wisselink 6,428,565.

Re claim 1, Wisselink teaches a modular grafting system, col. 3 ll. 40-45, col. 4 ll. 59-68, comprising: a main body including a superior end and an inferior end, the superior end being sized to engage walls defining an aortic arch portion of vasculature, col. 3 ll. 40-45, col. 4 ll. 59-68, and further, col. 2 ll. 18-35, "depending on which regions

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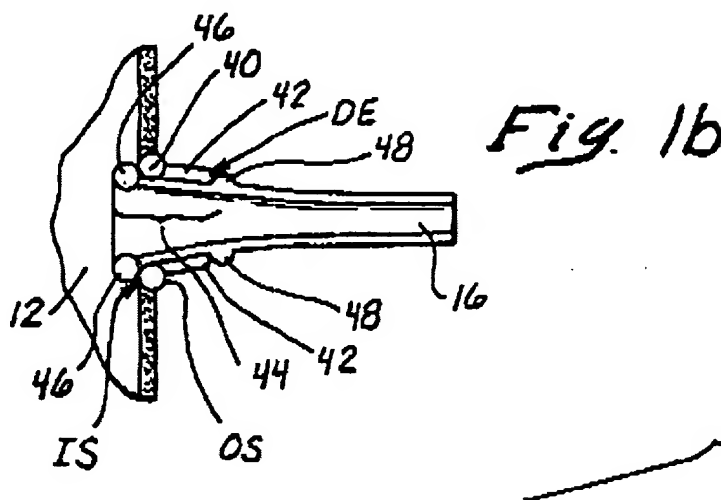
of the aorta are involved ... aneurysms involving the aortic arch and the branch arteries ... may be useable for endovascular grafting in regions of a blood vessel (e.g., aorta) from which branch blood vessels (e.g., carotid ... subclavian) ... extend", a first leg and a second leg extending from the main body, col. 4, ll. 50-56 "a bifurcated anatomical conduit (i.e., a conduit having a main portion, a first furcation, and a second furcation)", see also, fig. 2a, the first leg being longer than the second leg, see again, fig. 2a; and an extension component, col. 4, ll. 1-22, "a branch graft", the extension component being sized to mate with the second leg after placement of the main body within vasculature, col. 4 ll. 1-22, "second connector being engageable with said first connector to connect the proximal end of the second pliable tube to the first pliable tube such that fluid which flows through the lumen of the primary graft may pass through said branch opening and into the lumen branch graft."

Re claim 2, Wisselink teaches the main body further comprising a plurality of stents attached thereto, fig. 1f, elements 16, "branch grafts", where extension component can be considered either a) the branch grafts 16 or b) the connector portion 17 of the device.

Re claims 3 and 4, Wisselink teaches the main wherein certain of the plurality of stents are attached to the exterior or interior of the main body, col. 3, ll. 60-68, "a primary graft anchoring device ... a radially expandable stent, frame, series of rings, and/or adhesive, sutures, staples, etc ... for holding the graft in place. In the case of sutures or staples, the stents would be attached to the exterior AND interior (through the

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weaving or interlacing of the element); furthermore, fig. 1b shows the connection occurs at element 42 on the interior, and at ring 48, on the exterior, of the main body.



Re claim 5, Wisselink teaches the stents are self-expanding, col. 8, ll. 10-15.

Re claim 6, Wisselink teaches at least one stent including structure for attaching the main body to the vasculature, col. 7 ll. 65-68, col. 8, ll. 1-16.

Re claim 7, Wisselink teaches the first leg is sized to extend to and engage an interior surface of a vessel branching from the aortic arch, col. 2 ll. 18-35, "depending on which regions of the aorta are involved ... aneurysms involving the aortic arch and the branch arteries ... may be useable for endovascular grafting in regions of a blood vessel (e.g., aorta) from which branch blood vessels (e.g., **carotid ... subclavian**) ... extend", col. 4, ll. 50-56 "a bifurcated anatomical conduit (i.e., a conduit having a main portion, a first furcation, and a second furcation)".

Re claim 8, Wisselink teaches the first leg further including anchoring structure that attaches the first leg within the branch vessel, col. 8, ll. 1-16, "alternatively, they may be formed as separate structures ... self-expanding or pressure-expandable stents

... which are positioned within the lumens of the ... branch grafts to accomplish the desired anchoring.”

Re claims 9, 10 and 11, Wisselink teaches a delivery catheter sized to receive the main body and to be advanced through a branch vessel extending from the aortic arch, col. 8, ll. 55-65, “on a balloon catheter or other suitable delivery catheter capable of carrying the primary graft ... and any separate graft anchoring devices) to the intended site of implantation” ... further, col. 8 ll. 33-45 “required a ... graft to be passable through such branch graft openings ... e.g. carotid, subclavian). Wisselink teaches the delivery catheter can include structure for releasing the superior end and second leg of the main body within the aortic arch, and the first leg within the branch vessel, col. 8 ll 55-60, also col. 2 ll. 18-35, “depending on which regions of the aorta are involved ... aneurysms involving the aortic arch and the branch arteries ... may be useable for endovascular grafting in regions of a blood vessel (e.g., aorta) from which branch blood vessels (e.g., **carotid ... subclavian**) ... extend”. Also see fig. 2a, 2b.

Re claim 12, Wisselink teaches a supplemental delivery catheter sized to receive the extension component and to be advanced upstream within an aorta to the aortic arch, col. 9 ll. 14-25.

Re claim 13, Wisselink teaches the supplemental delivery catheter including a releasing mechanism that accomplishes deploying the extension component at least partially within the second leg of the main body; col. 9 ll. 14-25, balloon can be inflated, causing the purse string suture to break and the branch graft to radially expand, or, snap-fit connection.

Re claim 14, Wisselink teaches (in fig. 2c) the extension component 14 further comprising a first anchoring device 40, 42, 46, 48 and a second anchoring device 20, the first anchoring device being sized to engage the second leg of the main body 12a and the second anchoring device being sized to engage interior walls of the aorta 20.

Re claim 15, Wisselink teaches the anchoring devices are self-expanding, col. 8, ll. 1-16, "alternatively, they may be formed as separate structures ... self-expanding or pressure-expandable stents ... which are positioned within the lumens of the branch grafts to accomplish the desired anchoring."

Claim Rejections - 35 USC § 103

5. Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by Wisselink 6,428,565 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wisselink 6,428,565.

Wisselink teaches the device as claimed and as discussed above.

It should further be noted that it has been held that changes in size, proportion and the optimization of results-effective variables have all been held obvious. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976), 531 F.2d at 1053, 189 USPQ at 148.). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is

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the optimum combination of percentages.”); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969. For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05. The length of the respective “legs” of the main body can be considered results-effective variables that would be within the purview of one of ordinary skill in the art to alter.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See references cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan R. Stroud whose telephone number is 571-270-3070. The examiner can normally be reached on Monday through Friday, 7:30 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan Stroud/
X 0-3070

Thomas J Sweet
Primary Examiner
AU 3774
